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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,752	01/17/2002	Norbert A. Gschwend	33809	9021

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EXAMINER
FLOOD, MICHELE C

ART UNIT	PAPER NUMBER
1654	8

DATE MAILED: 04/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/889,752	Gschwend et al.
Examiner	**Art Unit**
Michele Flood	1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Feb 19, 2003*.

2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-8 and 16-27* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-8 and 16-27* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Acknowledgment is made of the receipt and entry of the amendment filed on February 19, 2003. Acknowledgment is made of Applicant's cancellation of Claims 9-15, and newly added Claims 16-27.

Claims 1-8 and 16-27 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24 and 27 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Newly applied as necessitated by amendment.

Claim 24, line 5, is rendered vague and indefinite by the term "alicuia mechanica" because the term is unsearchable. The examiner's preliminary analysis and extensive search demonstrates that the claimed subject matter cannot be adequately searched by class or keyword among patents and typical sources of non-patent literature.

Although not rising to the level of uncertainty, Claim 27 is rendered not grammatically correct by the recitation of the numerous "and" that appear in lines 2-5. Applicant may overcome the rejection by deleting "and" in lines 2-5.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-8 and 16-27 remain/are rejected under 35 U.S.C. 103(a) as being unpatentable over Ljunggren (P) and/or Mallasz (A) in view of Gruenweld et al. (U), Kovacs (NN, HU 77312T), Li (JJ, CN 1130074), Stevens (B), McCarthy (S), Zimmer (T), Shen (II, CN 1174061), Borbely et al. (N, Abstract), Murase et al. (O), Vittone (C) and BE 723594 (Q), Iordachel et al. (R) and Lust (V). The rejection stands for the reasons set forth in the previous office action and for the reasons set forth below.

Applicant's arguments have been fully considered but they are not deemed persuasive because the cited references provide the suggestions and motivation to the claimed inventions.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, the primary references of Ljunggren and Mallasz were relied on for the reasons set forth in

the previous Office action, and for the reasons set forth below. Firstly, Ljunggren teaches a pharmaceutical composition for treating rheumatism and dermatosis comprising FeS (0.1 to 5%); FeS (0 to 4%) and sulphur (0 to 4%), which was prepared by mixing the dry substances with an inert dispersing agent and was applied directly to the diseased spot. Secondly, Mallasz teaches an anti-rheumatic pharmaceutical composition comprising sulfur, and a method of making thereof. The referenced composition comprises one or more metallic substances (e.g., copper and sulfur), which is used as an antispasmatic product for the treatment of rheumatism and related rheumatic disorders (see Column 2, lines 4-16; Column 3, lines 46-59; and Column 7, lines 8-24). The compositions taught by Mallasz are in the form of various conventional pharmaceuticals, i.e., powder, liquid, gas and/or mixtures thereof, adhesive tapes, and plasters. In Column 8, lines 50-67, Mallasz teaches a "Rheumatic plaster" comprising sulphur and copper in various dose amounts. See the tables in Column 9, wherein Mallasz shows how effective the copper/sulfur plaster is in treating various rheumatic syndromes. Because neither Ljunggren nor Mallasz taught a pharmaceutical preparation further comprising mustard seed, a cupric salt, camomile, camphor, and potassium iodate, the secondary references of Greunweld, Kovacs, Li and Stevens were relied upon because each teaches compositions comprising mustard seed that are used for treating rheumatic syndromes, each of the secondary references of McCarthy, Zimmer and Shen were relied upon because teaches compositions comprising a cupric salt that are used for treating rheumatoid illnesses, each of the secondary references of Borbely and Murase were relied upon because each teaches compositions comprising camomile that are used for treating rheumatic

syndromes, each of the secondary references of Vittone and BE 723594 were relied because each teaches compositions comprising camphor that are used for treating rheumatic syndromes, and finally, the secondary reference of Iordachel was relied upon because Iordachel teaches a composition comprising potassium iodate that is used treating rheumatic syndromes. With regard to cupric salts, both of the secondary references of McCarthy and Zimmer were relied upon because each teaches topical compositions comprising copper sulfate, which are used for treating rheumatic syndromes, such as inflammatory and arthritic conditions. Furthermore, the secondary reference of Shen taught a method of making a Chinese medicine capsule for rheumatoid diseases comprising grinding, mixing and capsulizing herbal ingredients with calcined native copper. With regard to camomile, the secondary references of Borbely and Murase were relied upon because Borbely teaches an antirheumatic ointment comprising camomile oils (*Matricaria chamomilla*), and Murase teaches a pharmaceutical preparation that comprises an herbal extract of plants obtained from the body parts of the plant *Matricaria chamomilla*, which is used in the treatment of rheumatism and gout. Moreover, with regard to the claim limitation of Claim 20 wherein Applicant claims a process wherein the chamomile is chamomile flowers, the Office maintains that it also would have been obvious to one of ordinary skill in the art and one of ordinary skill in the art would have been have been motivated and would have had a reasonable expectation of success to add the claimed camomile ingredient in the form of flowers because at the time the invention was made it was well known in the art that camomile flowers are the medicinal part of the camomile plant, as evidenced by the teachings of Lust on page 144 under the headings

"CAMOMILE (a) (*Anthemis nobilis)*" and "CAMOMILE (b) (*Matricaria chamomilla)*". Lust also teaches, on page 144, lines 24-25, that "The flowers can also be made into a rubbing oil for swellings, callouses, and painful joints." Further note that on page 287, Lust teaches the use of mustard (*Brassica spp.*) in cases of rheumatism, sciatica, peritonitis, neuralgia, and various internal inflammations. Furthermore, on page 288, lines 1-10, Lust teaches a method of making and the use of a mustard powder plaster for application to the skin. With regard to camphor, the secondary reference of Vittone was relied upon because Vittone teaches an external composition comprising 10/16 ounces of camphor and 1/16 ounces of mustard oil, which is used of the treatment of inflammation of joints as in arthritis, bone degeneration and bursitis. Similarly, BE 723594 teaches topical compositions containing (0.2-1%) camphor for the treatment of rheumatism, eczema, aches, and sunburns. Finally, with regard to potassium iodate, the secondary reference of Iordachel was relied upon because Iordachel teaches a wound-healing promoting agent comprising potassium iodate.

With regard to newly added Claims 17-22, wherein Applicant claims a process for producing a pharmaceutical preparation useful for the treatment of rheumatic syndromes, wherein the process comprises the steps of: mixing components comprising talc and sulfur into a powder form; and adding catalytic powder to the powder form; wherein the catalytic powder is a pulverulent mixture comprising talc, mustard seed and copper sulfate, the Office still relies upon the cited prior art references for the reasons set forth above and for the reasons set forth in the previous Office action. For instance, although the combined teachings of the cited references set

forth above do not appear to teach the particular process steps, the Office maintains that the adjustment of particular working conditions (e.g., determining the result-effective ratio of ingredients to an additive such as "talc" in the making of pharmaceutical forms for administration; as well as the amount and/or duration of the pharmaceutical preparation to be administered based upon the form of the pharmaceutical preparation to be used- e.g.; foot powder, plaster, poultice, capsules, etc. - such as beneficially disclosed by one or more of the cited references; as well as the particular order of mixing, and blending the ingredients to be used in the making of the pharmaceutical), is deemed merely a judicious selection and routine optimization which would have been well in the purview of either one of ordinary skill in the art or the skilled artisan at the time the invention was made.

With regard to newly added Claims 24-26, wherein Applicant claims a method for treating a disorder, wherein said method comprises the step of administering to a human the claim-designated pharmaceutical preparation, the Office relies upon the cited prior art references which teach the ingredients that are effective in the treatment of rheumatic syndromes. Hence, at the time the invention was made, one of ordinary skill in the art would have been motivated and one of ordinary skill in the art would have had a reasonable expectation of adding any of the pharmaceutical preparations comprising mustard seed taught by Greunweld, Kovacs, Li and Stevens, adding any of the pharmaceutical preparations comprising cupric salts taught by McCarthy, Zimmer and Shen, adding any of the pharmaceutical preparations comprising camomile taught by Borbely and Murase, adding any of the pharmaceutical preparations

comprising camphor taught by Vittone and BE 723594, and adding the pharmaceutical preparation comprising potassium iodate taught by Iordachel to the pharmaceutical preparation taught by Ljunggren and/or Mallasz to provide the claimed invention because mustard seed, cupric salts, camomile, camphor, and potassium iodate were known as ingredients having the beneficial functional effect of treating rheumatic syndromes, as evidenced by the referenced teachings. Moreover, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the instantly claimed ingredients for their known benefit since each is well known in the art for their claimed purpose and for the following reasons. This rejection is based on the well established proposition of patent law that no invention resides in combining old ingredients of known properties where the results obtained thereby are no more than the additive effect of the ingredients, *In re Sussman,* 1943 C.D. 518. Applicants invention may be predicated on an unexpected result, which typically involves synergism, an unpredictable phenomenon, highly dependent upon specific proportions and/or amounts of particular ingredients. Any mixture of the components embraced by the claims which does not exhibit an unexpected result (e.g., synergism) is therefore *ipso facto* unpatentable. Thus, at the time the invention was made, one of ordinary skill in the at would have been motivated and one would have had a reasonable expectation of success to add any of the claimed ingredients taught by either Ljunggren and/or Mallasz to the claimed ingredients taught by Gruenweld, Kovacs, Li, Stevens, McCarthy, Zimmer, Shen, Borbely, Murase, Vittone, BE 723594, and Iordachel in the making of the claimed pharmaceutical preparations having the claimed functional effect because

the claimed invention is no more than the combining of well known ingredients used in well known methods for the treatment of rheumatic syndromes, as further evidenced by the teachings of Lust. Therefore, the instant claims, in the range of proportions where no unexpected results are observed, would have been obvious to one of ordinary skill having the above cited references before him. Thus, contrary to Applicant's argument that the Office has failed to establish a prima facie case of obviousness is rebutted in full because, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed inventions, as evidenced by the references, especially in the absence of evidence to the contrary.

Thus, with the primary references of Ljunggren and Mallasz providing the motivation of using pharmaceutical preparations comprising sulfur and copper for the treatment of rheumatic syndromes; and with Gruenweld teaching a method of making an external antirheumatic preparation comprising a mustard plaster; and with Kovacs teaching a rheumatic and muscular painkilling composition comprising mustard seed; and with Li teaching a medicinal powder of mustard seed, which is prepared by mixing, crushing, and sieving herbs into a mixture of powder; and with Stevens teaching a topical foot powder comprising seeds of mustard and camphor which provide a sense of warmth to painful areas for treatment for muscle pain and arthritis; and with McCarthy and Zimmer teaching compositions comprising copper sulfate that are used for treating rheumatic syndromes, such as arthritis and inflammatory conditions; and with Shen teaching a method of making a Chinese medicine for rheumatoid diseases comprising grinding, mixing herbal ingredients with calcined native copper; and with Borbely teaching an antirheumatic ointment

comprising camomile oils; and with Murase teaching a pharmaceutical composition comprising an herbal extract of containing the body parts of chamomile for the treatment of rheumatism; and with Vittone teaching an external composition comprising camphor and mustard oil for the treatment of inflammation of joints as in arthritis, bone degeneration and bursitis; and with BE 723594 teaching a topical composition for the treatment of rheumatism, eczema, aches and sunburns; and, finally with Iordachel teaching a wound-healing promoting agent comprising potassium iodate, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the instantly claimed old and well-known ingredients to provide a composition for the use as a composition for the treatment of a rheumatic disorder, as suggested by the cited references. As each of the references clearly indicate that the various proportions and amounts of the ingredients used in the claimed composition or the claimed composition/pharmaceutical combinations are result variables, they would have been routinely optimized by one of ordinary skill in the art in practicing the invention disclosed by that reference. Therefore, the invention as a whole was clearly prima facie obvious in the absence to the contrary.

No claims are allowed.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michele Flood whose telephone number is (703) 308-9432. The examiner can normally be reached on Monday through Friday from 7:15 am to 3:45 pm. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600 receptionist whose telephone number is (703) 308-0196 or the Supervisory Patent Examiner, Brenda Brumback whose telephone number is (703) 306-3220.

MCF

April 15, 2003

CHRISTOPHER R. TATE
PRIMARY EXAMINER